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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,521	06/04/1999	MARK F. PITTENGER	640100-326	3211

7590 11/04/2002

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EXAMINER

DECLoux, AMY M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/319,521

Applicant(s)

PITTENGER ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-13, 36, 39 and 60-79 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-13, 36 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 8-15-02 (Paper No. 13), for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/319521, is acceptable and a CPA has been established. An action on the CPA follows.

### ***Election/Restrictions***

Claims 1-3, 5-13, 36, 39 and 60-79 are pending.

Applicant's election of Group II, claims 14-16, 18-27, 29-35, 37-38 and 40-41 in Paper No. 6, filed 10-27-01, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). This election, made in response to a restriction requirement presented in the parent case, has been maintained. It is noted that claims 14-16, 18-27, 29-35, 37-38 and 40-41 have been cancelled and replaced by claims 60-79, which are presently under consideration.

Claims 1-3, 5-13, 36 and 39 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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Claims 60-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnstone et al (US Patent #5,908,784), as evidenced by [www.voigtglobal.com/Cellgro\\_basal\\_liquid.htm](http://www.voigtglobal.com/Cellgro_basal_liquid.htm).

The '784 patent teaches a process for producing chondrocytes from mesenchymal stem cells and a process for inducing chondrogenesis in mesenchymal stem cells comprising culturing human mesenchymal stem cells in vitro in a three dimensional format with at least one chondroinductive agent. The mesenchymal stem cells are preferably isolated, culture expanded human mesenchymal stem cells in a chemically defined serum free environment and are condensed in close proximity, such as in the form of a three dimensional cell mass, e.g. packed cells or a centrifugal pellet or in a ceramic cube. The chondroinductive agent is preferably selected, individually or in combination from the group consisting of I) a glucocorticoid such as dexamethasone; ii) a member of the transforming growth factor beta super family such as BMP-2 or BMP-4, TGF-beta1; iii) a component of the collagenous extracellular matrix such as collagen I; and IV) a vitamin A analog such as retinoic acid. Particularly preferred is the combination of dexamethasone and TGF-Beta-1, (see entire patent, especially column 2, lines 5-33, and column 9, lines 45-50).

The '784 patent further teaches that the serum free media comprises a chemically defined minimal essential medium, ascorbate or an analog thereof, an iron source, insulin or an insulin like growth factor, in an Eagle's based media such as DMEM (column 6, lines 42-45, column 4, lines 26-34, column 2, lines 43-53). [www.voigtglobal.com/Cellgro\\_basal\\_liquid.htm](http://www.voigtglobal.com/Cellgro_basal_liquid.htm) teaches that DMEM contains from 1 to 4.5 g/L glucose. Therefore, the referenced teachings anticipate the claimed invention.

### ***Response to Arguments***

Applicant's arguments filed 8-15-02 (Paper No. 14) have been fully considered but they are not persuasive. Applicant states that they have discovered that by culturing mesenchymal stem cells in a chondrogenic medium which includes a simple sugar at a concentration of from about 3 g/L to about 7 g/L, one obtains improved differentiation of mesenchymal stem cells into chondrocytes, as opposed to media which have a lower sugar concentration of 1 g/l in "low glucose DMEM".

Applicant contends that though the referenced art taught by Johnstone states that a glucose-containing medium such as DMEM may be used, Johnstone does not disclose or even remotely suggest to one of ordinary skill that the chondrogenic medium may include a simple sugar in an amount of from 3 g/L to about 7 g/L. However as noted in the rejection above, DMEM typically contains with 1 to 4.5 g/L of glucose. Sigma teaches that the original DME formula contains 1 g/l of glucose and that 4.5 g/l of glucose has proved to be optimal in cultivating certain cell types (see attached DMEM Product information from Sigma).

Applicant further contends that DMEM-low glucose has a glucose concentration of 1 g/l, is the preferred embodiment of Johnstone (column 6), and thus teaches away from the present invention. However, the examiner notes that Johnstone does not designate DMEM-low glucose as a preferred embodiment. The examiner also notes that Johnstone discloses in column 4 that

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DMEM is an example of a minimal essential medium (MEM) that will support the viability of human mesenchymal stem cell in vitro, and also discloses in columns 5 and 6 that DMEM-low glucose is one example of several media which are particularly well suited to a medium that can be used in the selective attachment/isolation of mesenchymal cells. Therefore the exemplification of one medium does not teach away from the present invention, especially given that DMEM is typically contains 4.5 g/L glucose.

***Conclusion***

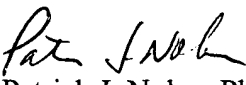
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
October 30, 2002

  
Patrick J. Nolan, Ph.D.  
Primary Patent Examiner,  
Group 1640